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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Justin St. John

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FULBRIGHT AND JAWORSKI LLP
555 S. FLOWER STREET, 41ST FLOOR
LOS ANGELES, CA 90071

EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,354

Applicant(s)

ST. JOHN ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/15/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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Applicant's arguments filed August 15, 2007 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1, 3-5 and 8-25 are pending.

The amendment filed August 15, 2007 has changed the grouping of claims for restriction purposes. The new groupings are:

- I. Claims 1-5, 19 and 20.
- II. Claims 8-13.
- III. Claims 14-18, 20 and 23
- IV. Claims 21-25

Therefore, in view of applicant's election of group I in the reply filed February 26, 2007, the withdrawn claims are 8-25 and examined claims are 1-5, 19 and 20.

Entry 1, page 2 of the IDS filed August 15, 2007 does not comply with 37 § CFR 1.98(a)(1), and, therefore, has not been considered.

The rejection of claim 24 under 35 U.S.C. 101 made in the office action mailed April 20, 2007 because the claimed invention is directed to non-statutory subject matter is withdrawn.

The rejection of claims 1, 3 and 5 under 35 U.S.C. 102(b) as being clearly anticipated by Levy et al. (1999) Transgenic Res., Vol. 8, pp. 137-145 made in the office action mailed April 20, 2007 is withdrawn.

The rejection of claims 1, 2, and 4 under 35 U.S.C. 103(a) as being unpatentable over Sims et al. (1993) Proc. Natl. Acad. Sci., Vol. 90, pp. 6143-6147 and Levy et al. (1999) Transgenic Res., Vol. 8, pp. 137-145 in view of Hiendleder et al. (1999) Molec. Reprod. Develop. Vol. 54, pp. 24-31 made in the office action mailed April 20, 2007 is withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 19 and 20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of production a viable hybrid mammalian cell having a single functional mitochondria population comprising the step of introducing genomic DNA from a mitochondrially depleted mammalian donor cell in to a recipient mammalian cell of the same species from which genomic DNA has been removed, does not reasonably provide enablement for the method for any cell or transpecies mitochondria for reasons set forth in the office action mailed April 20, 2007. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Meirelles demonstrates that methods of nuclear transfer where the nuclear material of *Bos indicus* is inserted into the oocyte of *Bos taurus* produces calves comprising the nuclear material of *Bos indicus* and the mitochondria of *Bos taurus*. Meirelles *et al.* teach that previous attempts to use the *Bos* oocyte as hosts for nuclear transfer from unrelated species allowed development to the blastocyst stage, and conclude that incompatibility among the nuclear and mitochondrial genetic systems is responsible for the early arrest. Meirelles *et al.* also point to similar failures using *Mus caroli* and *Mus musculus* citing Dominko *et al.* Meirelles *et al.* conclude that in light of their results and the failures of the prior art, that nuclear transfer across subspecies barriers is possible. (see Meirelles, pp. 351-355). As the disclosed use of the method is for nuclear transfer to produce identical offspring, there must be a reasonable correlation between the disclosure and the claims.

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Thus at the time of the instant invention, the skilled artisan would have needed to engage in an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

The claims have not been amended to indicate the recipient and donor cells are of the same species. As taught by Meirelles, oocyte mitochondria from a species different from the donor nucleus do not support development of the reconstituted embryo. It is noted that the examples in the specification are for same species nuclear transfer. In particular, example 4 discloses the transfer of a nucleus from a sheep mitochondria depleted cell into a sheep enucleated oocyte.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states "zygote cell," but a zygote by definition is a single cell. Thus it is confusing as to applicant's meaning of the term "zygote cell." Further, it is not clear that the cytoplasm of an oocyte or 2-cell embryo cell would produce a "zygote" upon transfer of a donor nucleus.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 19 and 20 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Meirelles et al. (2001) Genetics, Vol. 158, pp. 351-356 for reasons set forth in the office action mailed April 20, 2007.

Claims 19 and 20 are products produced by a particular process. The products are "old" known in the art at the time of filing. Thus, the products claimed would only be patentable if there was a patentable distinction between them. There is no evidence on the record that cells and animals made by the claimed method have any new property or structure imbued by the method.

Meirelles teaches a *Bos indicus* calf cloned by transfer of a *Bos indicus* blastomere into an enucleated *Bos taurus* oocyte (page 353, col. 1, parag. 1, lines 7-16). The cells of the resulting calf contain only *Bos taurus* mitochondria (page 354, col. 1, parag. 1, lines 11-18; and Figure 3, lines 11-12).

Applicant argues the hybrid zygote will inevitably contain two mitochondrial populations, respectively, derived from the host and donor cells. Applicant argues it is well known that cattle are heteroplasmic due to two populations of mitochondria being present in the oocytes. Applicant argues the method of Meirelles could result in 3 different populations of mitochondria. Applicant argues some of the calves produced by Meirelles have only one population of mitochondria because mtDNA from the donor is gradually lost during development. Applicant argues this would result in animals where some mitochondrial DNA had been eliminated in some tissues but not all. These arguments are not persuasive.

Meirelles states the calf born contained only *Bos taurus* mitochondria. How the calf was produced to contain only one species mitochondria does not affect the product. In a side-by-side comparison, no difference has been disclosed in the present specification and none can be observed between the calf of Meirelles and that which falls within the scope of the claim 20. Applicant needs to provide evidence that that calf of Meirelles contained

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multiple mitochondria populations in view of the clear statement of Meirelles. With regard to the zygote cell, evidence has not been presented that the one-cell embryo of Meirelles that developed into the cloned calf was not a mitochondrial homoplasmic embryo. There is no indication in Meirelles as to how many embryos were analyzed for mitochondrial content to eliminate any possibility of homoplasmy in a one-cell embryo.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah Crouch, Ph.D.
Primary Examiner
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October 22, 2007